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FedEx Express

February 04, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD, 20852

RE: **Supplemental Comments,** Docket No. 2004G-0381, Draft Guidance for Records Access Authority, Federal Register notice December 9, 2004

Dear Sirs and Madams:

These supplemental comments are submitted on behalf of Federal Express Corporation (FedEx Express) and FedEx Trade Networks Transport and Brokerage (FTN), hereinafter collectively referred to as "FedEx". FedEx submitted comments previously on January 24, and these supplemental comments cover an additional topic that has come to light since filing of our original comments.

FedEx supports the FDA in its activities to secure and protect the U.S. food supply chain from bioterrorism attack and other public health emergencies. The draft Guidance Document that is the subject of this Federal Register notice is another good resource to identify and explain to the affected members of the food supply chain how FDA intends to administer these provisions. However, FedEx believes that the method of notification to the transporter or broker as proposed by FDA in this Guidance Document must be revised to provide for notification to the specific agent or department of the company responsible for these records in order to allow for timely response to FDA, in order to perform traceback of the shipment as necessary.

The FDA Guidance Document states that the FDA will present a written notice "...to the owner, operator, or agent in charge....", and inform that person of the FDA's authority to obtain these records. This statement is not sufficient to identify precisely to what party FDA will present this notice, and at what location. FDA may be considering presenting this notice to a local station of a national carrier or broker, perhaps on the basis that a shipment in question may have transited that specific facility; however, mere handling by a specific facility does not mean that facility will retain or have access to all required records, especially when FDA allows for alternative record keeping processes, as under these regulations. FDA must identify a more specific process to provide for submission of the notice to a specific party of each carrier or broker, who will have knowledge of and access to the required records, in order to respond within the required 24 hour time frame.

2004G-0381 SUP 1

The FDA regulations covering this do not provide any clarity on the specific procedure, stating only that records must be provided within 24 hours from "....time of receipt of the official request..." from an officer or employee who presents appropriate credentials "and a written notice." (21 CFR 1.361).

Large transporters such as FedEx Express have thousands of physical locations in the U.S. Records are maintained in centralized locations for economic reasons, and as allowed by various respective regulatory bodies. Records demands presented to a local terminal will cause delays in response, while the local terminal works to identify the internal department that maintains these records and relays the request to that department. This same issue applies to any party required to keep records with multiple locations in the U.S. We recommend that FDA establish a joint effort with the transport industry to identify a process that will provide for submission of the FDA request directly to the centralized department within the carrier that can respond to the request quickly, in order to provide the data that FDA needs and requires.

FedEx would like to reiterate our support of the FDA in their efforts to secure the U.S. food supply chain, and for the opportunity to submit supplemental comments to this Guidance Document.

Sincerely,

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